REMARKS

Claims 4, 6 and 19 are now pending in this application. The amendments to the claims are identical to those proposed in the Amendment After Final filed on December 6, 2004.

The continuation sheet attached to the Advisory Action mailed on November 3, 2004, stated that the specification did not literally support the treatment of a "human" who exhibits normal or low blood pressure. The undersigned spoke with the Examiner by telephone on November 5, 2004, to discuss this question of written description support, and the Examiner invited the undersigned to provide comments on the issue in this supplemental paper. Applicants filed arguments directed to this question of written description support in the Amendment dated December 6, 2004. The continuation sheet attached to the Advisory Action mailed on January 24, 2005, claimed that the specification did not provide written description support for the treatment of a human. The Examiner alleged that an incorporation by reference to JNC VI, which concerns the study, detection and prevention of hypertension in humans, was an improper incorporation by reference of "essential material." Applicants continue to traverse this rejection.

The "fundamental factual inquiry" in the written description analysis is "whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." MPEP § 2163.02. The specification provides written description support for the amended claims, including support for reciting a "human" who exhibits normal or low blood pressure. For instance, and as mentioned by the Examiner, the specification in the fourth full paragraph on page 3 mentions that a suitable definition of normal or low blood pressure can be found in JNC VI, which was incorporated by reference. A copy of JNC VI has been provided to the Examiner. It is clear that the entire document concerns the study, detection and prevention of hypertension in humans. Table 2 on page 11 of the attachment illustrates a classification of blood pressure for "adults age 18 and older." Page 12 of the attachment discusses techniques for blood pressure measurement of patients, as well as instructions to clinicians to explain to patients the meaning of their blood pressure readings. There should be no question at all that these patients are human. The present specification obviously conveys the use of the invention on humans by referring to the JNC VI disclosure for a suitable definition of normal or low blood pressure.

The incorporation by reference of JNC VI is not an improper incorporation by reference of essential material. Essential material is defined in MPEP § 608.01(p) as that which is necessary to describe the claimed invention or provide an enabling disclosure or best mode of the invention. In this instance, the text of JNC VI does not need to be added to the specification to serve as a description of the invention. In the most recent Amendment, applicants explained the JNC VI disclosure in significant detail. This was done to make it clear to the Examiner that those skilled in the art regard its teachings as directed to humans, and that those skilled in the art would have recognized it as such when seeing it cited in the current application. The patent specification, by itself, therefore conveys the use of the invention on humans by referring to the JNC VI disclosure for a suitable definition of normal or low blood pressure in a patient population to be treated according to the invention. Applicants have nonetheless amended the specification to include certain pertinent portions of JNC VI. This amendment does not introduce new matter and, as indicated above, is the material incorporated by reference.

The reference to JNC VI is not the only portion of the specification that conveys the use of the invention on humans. For instance, the Example on page 10 of the specification mentions the clinical study that "was conducted in 267 centres in 19 countries over a six year period and included 9,541 participants who are at high risk for cardiovascular events due to a history of previous ischaemic heart disease, stroke, peripheral arterial disease or individuals with diabetes." One skilled in the art reading such a disclosure would understand that the "participants" of such a study were humans. One skilled in the art would also understand that "individuals with diabetes" refers to humans with diabetes. Applicants remind the Examiner that this question of written description support is not whether the application text contains the word "human," but whether the disclosure shows that the inventors were in possession of the method now claimed. MPEP § 2163. If the Examiner maintains this rejection, applicants respectfully request that the Examiner explain why the disclosure is not believed to show that the inventors had possession of the use of their method on humans.

The Examiner indicated that an Information Disclosure Statement filed on November 8, 2004, has not been entered. Applicants did not file an Information Disclosure Statement on November 8, 2004. According to the PAIR records of this application, a third party filed a Petition for Access to this application on November 8, 2004, and included two pages of a

PTO 1449 form filed in a separate application. Those two pages, having the document description of "Information Disclosure Statement," are quite clearly not part of any Information Disclosure Statement filed in the present application.

The arguments above relate to concerns raised by the Examiner in the Advisory Actions. The Final Office Action raised a number of art-based rejections, and applicants have already responded to those art rejections in the Amendment After Final filed on October 6, 2004. For the convenience of the Examiner, applicants repeat those arguments below.

Rejection of claim 4 under 35 U.S.C. § 103(a)

The Examiner maintained the rejection of claim 4 under 35 U.S.C. § 103(a) in view of U.S. Patent No. 4,587,258 and the Merck Manual. Applicants disagree with this rejection for the reasons already made of record. Applicants have nonetheless incorporated the subject matter of canceled claim 18 into claim 4. Claim 18 was not included in this obviousness rejection. This rejection should therefore be withdrawn as it relates to amended claim 4.

Rejection of claims 6-7 and 19 under 35 U.S.C. § 103(a)

The Examiner maintained the rejection of claims 6-7 and 19 under 35 U.S.C. § 103(a) in view of U.S. Patent No. 4,587,258, the Merck Manual and WO 96/24373. Applicants disagree with this rejection for the reasons already made of record. The subject matter of claim 18, which has been added to independent claim 4, was not included in this obviousness rejection. Claim 6 and 19 depend from amended claim 4, and for at least this reason should not be obvious in view of the cited documents.

Rejection of claims 4 and 18 under 35 U.S.C. § 102(b)

The Examiner maintained the rejection of claims 4 and 18 under 35 U.S.C. § 102(b) in view of Allen et al. Applicants again respectfully traverse this rejection.

Allen discloses a study of the role of angiotensin converting enzyme inhibition with ramipril on mesenteric vascular hypertrophy and urinary albumin excretion in a normotensive model of experimental diabetes. The authors conclude that ramipril will attenuate the development of mesenteric vascular hypertrophy after 24 weeks of experimental diabetes. The document does not disclose reducing the risk of onset of

congestive heart failure and does not even appear to discuss the details of any effects of ramipril on cardiac function generally.

In an effort to expedite prosecution, applicants have amended claim 4 to recite that the patient is human. Allen discloses experiments on rats, not humans. For at least this reason, the document does not anticipate the amended claims. Moreover, since the document does not suggest reducing the risk of onset of congestive heart failure in the human patient recited in the pending claims, Allen does not render the claims obvious.

Applicants believe that the pending claims are in condition for allowance. Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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